AMENDATORY SECTION

WAC 246-235-093 Manufacture, assembly or distribution of devices under general license. (1) An application for a specific license to manufacture or initially transfer or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under WAC 246-233-020((~~(4)~~)) or equivalent regulations of the United States Nuclear Regulatory Commission, an agreement state or a licensing state will be approved if:

(a) The applicant satisfies the general requirements of WAC 246-235-020;

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(i) The device can be safely operated by persons not having training in radiological protection;

(ii) Under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of ten percent of the limits specified in the table in WAC 246-221-010(1); and

(iii) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rems
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter	200 rems
Other organs	50 rems

(c) Each device bears a durable, legible, clearly visible label or labels approved by the department, which contain in a clearly identified and separate statement:

(i) Instructions and precautions necessary to assure safe installation, operation and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(ii) The requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(iii) The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(A) The receipt, possession, use and transfer of this device, Model . . . . . ., Serial No. . . . . Note*, are subject to a general license or the equivalent, and the regulations of the United States Nuclear Regulatory Commission or a state with which the United States Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of

this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

(Name of manufacturer or distributor)*

(B) The receipt, possession, use and transfer of this device, Model . . . . . ., Serial No. . . . . Note*, are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

(Name of manufacturer or distributor)*

*Note: The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(d) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in WAC 246-221-120, and the name of the manufacturer or initial distributor;

(e) Each device meeting the criteria of WAC 246-233-020(3)(k), bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in WAC 246-221-120.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the department will consider information which includes, but is not limited to:

(a) Primary containment (source capsule);
(b) Protection of primary containment;
(c) Method of sealing containment;
(d) Containment construction materials;
(e) Form of contained radioactive material;
(f) Maximum temperature withstood during prototype tests;
(g) Maximum pressure withstood during prototype tests;
(h) Maximum quantity of contained radioactive material;
(i) Radiotoxicity of contained radioactive material; and
(j) Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under WAC 246-233-020((~~(4)~~)), or under equivalent regulations of the United States

Nuclear Regulatory Commission, an agreement state or a licensing state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive in one year a radiation dose in excess of ten percent of the limits specified in the table in WAC 246-221-010(1).

(4) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to generally licensed persons shall, prior to the transfer to the intended user or the initial transfer to an intermediate person, if used:

(a) Furnish to the intended user and to each person to whom a device is transferred as an intermediary, the following:

(i) A copy of the general license contained in WAC 246-233-020((~~(4) to each person to whom the person directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in WAC 246-233-020(4)~~)). If WAC 246-233-020(3)(b), (c), and (d) or 246-233-020(3)(k) do not apply, those subsections may be omitted.

(ii) A copy of WAC 246-232-050, 246-221-230, 246-221-240, and 246-221-250; and

(iii) A list of the services that can only be performed by a specific licensee; (iv) Information on acceptable disposal options including estimated costs of disposal;

(b) Furnish to the intended user in another jurisdiction and to each person to whom a device is transferred as an intermediary, the following:

(i) A copy of the ((~~general license~~)) appropriate regulations, equivalent to WAC 246-233-020, 246-232-050, 246-221-230, 246-221-240, and 246-211-250, contained in the United States Nuclear Regulatory Commission's, agreement state's, or licensing state's regulation ((~~equivalent to WAC 246-233-020(4), or alternatively, furnish a copy of the general license contained in WAC 246-233-020(4) to each person to whom, directly or through an intermediate person, is transferred radioactive material in a device for use pursuant to the general license of the United States Nuclear Regulatory Commission, the agreement state or the licensing state~~)). If a copy of the general license in WAC 246-233-020((~~(4)~~)) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the United States Nuclear Regulatory Commission, agreement state or licensing state under requirements substantially the same as those in WAC 246-233-020((~~(4)~~)). If certain subsections do not apply to the particular device, those subsections may be omitted;

(ii) A list of the services that can only be performed by a specific licensee;

(iii) Information on acceptable disposal options including estimated cost of disposal;

(iv) The name or title, address, and phone number of the contact at the appropriate regulatory agency from which additional information may be obtained; and

(v) An indication that U. S. Nuclear Regulatory Commission policy is to issue high civil penalties for improper disposal;

(c) Report to the department all transfers of such devices to persons for use under the general license in WAC 246-233-020((~~(4)~~)) and all receipts

of devices from persons licensed under WAC 246-233-020.

(i) Such report shall ((~~identify~~)) include:

(A) The identity of each general licensee by name and mailing address ((~~, an individual by name and/or position who may constitute a point of contact between the department and the general licensee,~~)) for the location of use; if there is no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use;

(B) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(C) The date of transfer;

(D) The type ((~~and~~)), model number and serial number of device transferred, and

(E) The quantity and type of radioactive material contained in the device.

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user.

(iii) For devices received from persons generally licensed under WAC 246-233-020, the report must include:

(A) The identity of the general licensee by name and address;

(B) The type, model number, and serial number of the device received;

(C) The date of receipt; and

(D) In the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(iv) If the licensee makes changes to a device possessed by a person generally licensed under WAC 246-233-020, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(v) If no transfers have been made to or from persons generally licensed under WAC 246-233-020((~~(4)~~)) during the reporting period, the report shall so indicate.

(vi) The report shall cover each calendar quarter, shall clearly indicate the period covered by the report, and shall be filed within thirty days ((~~thereafter~~)) of the end of the calendar quarter.

(vii) The report shall clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(d) Reports to other departments.

(i) Report to the United States Nuclear Regulatory Commission all transfers of such devices to persons for use under the United States Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31 and all receipts of devices therefrom.

(ii) Report to the responsible department all transfers of devices manufactured and distributed pursuant to this section for use under a general license in that state's regulations equivalent to WAC 246-233-020((~~(4)~~)) and all receipts of devices from persons generally licensed under WAC 246-233-020 or equivalent.

(iii) Such reports shall ((~~identify~~)) include:

(A) The identity of each general licensee by name and mailing address ((~~, an individual by name and/or position who may constitute a point of contact between the department and the general licensee,~~)) for the location of use; if there is no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with

information on the actual location of use;

(B) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(C) The date of transfer;

(E) The type and model of the device transferred, and

(F) The quantity and type of radioactive material contained in the device.

(iv) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user.

(v) For devices received from persons generally licensed under WAC 246-233-020, the report must include:

(A) The identity of the general licensee by name and address;

(B) The type, model number, and serial number of the device received;

(C) The date of receipt; and

(D) In the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(vi) If the licensee makes changes to a device possessed by a person generally licensed under WAC 246-233-020, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(vii) The report shall be submitted within thirty days after the end of each calendar quarter in which such a device is transferred to the generally licensed person and shall clearly indicate the period covered by the report.

(viii) The report shall clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

((~~(iv)~~)) (ix) If no transfers have been made to United States Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the United States Nuclear Regulatory Commission.

((~~(v)~~)) (x) If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible department upon request of the department.

(e) Keep records ((~~showing the name, address and the point of contact for each general licensee to whom the person directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in WAC 246-233-020(4), or equivalent regulations of the United States Nuclear Regulatory Commission, an agreement state or a licensing state. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of subsection (4) of this section~~)) concerning transfers and receipts of devices that support the reports required by this section. Records required by this section shall be maintained for a period of three years following the date of the recorded event.

(f) If a notification of bankruptcy has been made under WAC 246-233-050 or the license is to be terminated, each person licensed under this section shall provide, upon request, to the department, the United States Nuclear Regulatory Commission, an agreement state, or a licensing state, records of final disposition required under subsection (4) of this section.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-235-093, filed 6/8/98, effective 7/9/98.]

AMENDATORY SECTION

WAC 246-235-095 Manufacture, assembly, or distribution of luminous safety devices, certain calibration sources or ice detectors under general license. (1) *Special requirements for the manufacture, assembly or repair of luminous safety devices for use in aircraft.* An application for a specific license to manufacture, assemble or repair luminous safety devices containing tritium or promethium-147 for use in aircraft for distribution to persons generally licensed under WAC ((~~246-233-020(5)~~)) 246-233-025 will be approved subject to the following conditions:

(a) The applicant satisfies the general requirements specified in WAC 246-235-020; and

(b) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, 32.101 of 10 CFR Part 32 or their equivalent.

(2) *Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under WAC* ((~~246-233-020(7)~~)) 246-233-035. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under WAC ((~~246-233-020(7)~~)) 246-233-035 will be approved subject to the following conditions:

(a) The applicant satisfies the general requirement of WAC 246-235-020; and

(b) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

(3) *Licensing the manufacture and distribution of ice detection devices.* An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under WAC ((~~246-233-020(9)~~)) 246-233-030 will be approved subject to the following conditions:

(a) The applicant satisfies the general requirements of WAC 246-235-020; and

(b) The criteria of Sections 32.61, 32.62, 32.103 of 10 CFR Part 32 are met.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-235-095, filed 6/8/98, effective 7/9/98.]

AMENDATORY SECTION

WAC 246-235-097 Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of WAC ((~~246-233-020(8)~~)) 246-233-040 will be approved if:

(1) The applicant satisfies the general requirements specified in WAC 246-235-020;

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(a) Iodine-125 in units not exceeding 10 microcuries each;

(b) Iodine-131 in units not exceeding 10 microcuries each;

(c) Carbon-14 in units not exceeding 10 microcuries each;

(d) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each;

(e) Iron-59 in units not exceeding 20 microcuries each;

(f) Cobalt-57 in units not exceeding 10 microcuries each;

(g) Selenium-75 in units not exceeding 10 microcuries each;

(h) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-

129 and 0.005 microcurie of americium-241 each.

(3) Each prepackaged unit bears a durable, clearly visible label:

(a) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries of hydrogen-3 (tritium); 20 microcuries of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each; and

(b) Displaying the radiation caution symbol described in WAC 246-221-120 (1)(a) and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for internal or external use in humans or animals."

(4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(a) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

(b) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a licensing state.

Name of manufacturer

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in WAC 246-221-170 of these regulations.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-235-097, filed 6/8/98, effective 7/9/98.]